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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,845	10/18/2001	Samy Ashkar	CMCC 779	7069

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EXAMINER

DEBERRY, REGINA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,845

Applicant(s)

ASHKAR ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 7-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Status of Application, Amendments and/or Claims

The information disclosure statement filed 23 September 2002 (Paper No. 6) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Applicant's election without traverse of Group I (claims 1-7) and species election (as it applies to Group I) SEQ ID NO:11 (claim 1), integrin 4 β 1 (claim 5) and stem cells (claim 6) in Paper No. 8 (07 April 2003) is acknowledged. The Examiner has withdrawn the species election requirement for claims 5 and 6.

Claims 8-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. In addition, claim 7 is withdrawn because SEQ ID NO:11 contains an RGD motif. The election was made **without** traverse in Paper No. 8. Claims 1-6 are under examination.

Claim Objections

Claims 1 and 6 are objected to because of the following informalities:

Claim 1 encompasses a non-elected invention (SEQ ID NO:) and requires amendment to limit to elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. No cells are excluded in claim 6, thus it does not further limit the parent claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "regulating cellular development" in claim 2 is a relative term which renders the claim indefinite. The term "cellular development" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Furthermore, the specification does not define what is meant by "regulating". It is unclear *how* SEQ ID NO:11 is changing cellular development.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an osteopontin-derived peptide consisting of the amino acid of SEQ ID NO:11 wherein said peptide regulates attachment and spreading of osteoprogenitor cells, does not reasonably provide enablement for an osteopontin-derived peptide comprising the amino acid of SEQ ID NO:11 which regulates cellular development, binds integrin receptors on the surface on any cell type. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are drawn to an osteopontin-derived peptide comprising amino acid SEQ ID NO:11, which regulates cellular development and binds integrins on various cell types such as tumor, macrophages, stem cells, endothelial cells and differentiated cells. The specification teaches that SEQ ID NO:11 is an osteopontin-derived fragment with cell attachment and/or cell spread activity (page 7, lines 23-27 and page 8, lines 11-20). The scope of the instant peptide encompasses the open (comprising) language of comprising SEQ ID NO:11 without distinguishing and limiting functions. The specification teaches when plates are coated with SEQ ID NO:11, human osteoprogenitor cells undergo a transformation from a neutral to a proactive condition in which the number of attached cells, as well as percent spread, significantly increases (specification, page 53, line 5-page 55). Cellular development is a complicated aspect of the living cell that entails a number of different biological activities/functions. Cell

attachment and cell spreading involves one facet in cellular development. The subject matter sought to be patented as defined by the claims is not supported by an enabling disclosure, because the term "cellular development" is not tantamount to "cell attachment and spreading". Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Furthermore, the specification only teaches that antibodies to $\alpha_v\beta_3$ integrin significantly diminishes mOC-1016 (SEQ ID NO:15) from binding to cells (page 53, lines 17-21 and page 54). The specification never discloses which integrin antibody would inhibit SEQ ID NO:11 from binding. There is no predictability as to which integrin receptor would bind SEQ ID NO:11 because the specification discloses that only antibodies to a specific integrin inhibited mOC-1016 from binding (table 8, page 54).

Lastly, the specification only discloses that when plates are coated with SEQ ID NO:11, human osteoprogenitor cells attach and spread to the surface. The specification fails to teach other cell types which have a SEQ ID NO:11 binding receptor. The instant claims encompass a number of diverse types of cells. It would require an indeterminate quantity of fundamentally unpredictable investigational experimentation of the skilled artisan to determine which integrin receptor bound SEQ ID NO:11 and then discern which cell type contained that specific receptor. Without sufficient guidance, the amount of experimentation would be undue for one skilled in this art. Thus only osteoprogenitor cells meet the limitations of the instant claim.

Due to the large quantity of experimentation necessary to demonstrate that SEQ ID NO:11 can regulate the many biological functions/activities of cellular development,

bind various integrins and discern the cell types which possess receptors for SEQ ID NO:11, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite any function limitations requirements of SEQ ID NO:11, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Young *et al.*, Genomics, 1990). Young *et al.* teach the cDNA, mRNA and deduced protein sequence of human osteopontin. Please see GenBank print out. Young *et al.* anticipate the instant claims because the specification teaches that SEQ ID NO:11 is an osteopontin-derived fragment and the instant claims read on open language (no size limitation on the claimed peptide). Furthermore, it is presumed that full length human osteopontin protein would have the same activity as recited.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
August 6, 2003



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